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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAMAN K. BAKSHI, KHALED J. BARAKAT, RAVI P. NARGUND, BRENDA L. PALUCKI, ARTHUR A. PATCHETT, IYASSU SEBHAT, ZHIXIONG YE, and LEONARDUS H.T. VAN DER PLOEG

Appeal 2005-1793
Application 09/990,499
Technology Center 1600

Decided: January 29, 2008

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge*, DONALD E. ADAMS, ERIC GRIMES, LORA M. GREEN, and NANCY J. LINCK, *Administrative Patent Judges*.

Opinion Dissenting filed by *Administrative Patent Judge* ADAMS.

PER CURIAM.

DECISION ON REQUEST FOR REHEARING

The Examiner requests rehearing of the Board's November 9, 2005 Decision on Appeal ("Decision") with respect to the Board's enablement and written description determinations (Request for Rehearing ("Request")). We have reconsidered the Decision pursuant to 35 U.S.C. § 6(b) and the points

the Examiner specifically raises and grant the requested rehearing. Upon rehearing, we affirm the Examiner's 35 U.S.C. § 112 ¶ 1 grounds of rejection.

The Examiner's Request raises the following issues: Did the Board misapprehend or overlook any points previously raised in the briefs such that the Board should rehear the appeal on the written record as supplemented by the Request? If so, at the time the claimed invention was made, would the Specification (i) have enabled the skilled artisan to make and use the full scope of the claimed invention and (ii) have provided an adequate written description of the claimed invention?

GRANT OF REHEARING

The prior panel reversed the rejections of the Examiner made under 35 U.S.C. § 112 ¶ 1 on November 9, 2005. The Examiner had rejected claims 39-75 under 35 U.S.C. § 112 ¶ 1 for failing to comply with both the enablement and written description requirements. In reversing both rejections, the panel stated:

> With both rejections we find that the examiner appears to have forgotten the election of species requirement she made on June 10, 2003 in Paper No. 9, and the appellants' election of "the species defined by Example 2 on page 75 of the specification" on June 26, 2003 in Paper No. 10. We point out that after making an election of species requirement, the proper course of action is for the examiner to examine the claims only with respect to the elected species, even when the claims are directed to a genus. That is, all claims which read on the elected species are examined as if they were directed exclusively to said species. Thus, in examining claim 39, for example, the relevant issue is whether the specification

> provides an adequate written description and an enabling disclosure of a method of treating erectile dysfunction which comprises administering a therapeutically effective amount of the compound defined by Example 2 on page 75 of the specification, to a male subject. Once it has been determined that the elected species has been described and is enabled by the specification, the examiner can either (i) allow any pending or newly-submitted claims directed only to said species; or (ii) move on to the next elected species and begin the examination process with respect to that species. Eventually, the examiner may determine, based on the number of species found to be patentable, that the genus claims are also allowable. While we make no comment on whether the election of species requirement was appropriate, we do direct the examiner's attention to M.P.E.P. §§ 808.01 (a) and 809.02(a). In any event, since the examiner has not provided any reasons as to why the elected species is not adequately described or enabled by the specification, Rejections II and III are reversed.

(Decision 5-7.)

The Examiner has entered a Request for Rehearing by an expanded panel. The Examiner argues that based on the fact that no art rejection was made for the elected species, and the fact that the Examiner stated that Appellants were in possession and enabled not only for the particular species of Example 2, but also for all of the species encompassed by formula I, the prior panel should have "inferred" that the Examiner examined the rest of the disclosed species (Request[1] 4-5).

According to the Examiner, if "the Examiner's rejections remain reversed, the application will be allowed and Applicants will be granted patent protection for broad claims without resolution of the issue as to

[1] We note that the pages of the Request are not numbered. Thus, for purposes of this opinion, page 1 of the request corresponds to the page entitled "REQUEST FOR REHEARING."

whether the full scope of the claims has been adequately described or enabled by the specification." (*Id.* at 3.) Appellants did not submit a response to the Examiner's Request.

The prosecution in this case has been confusing. The Examiner issued a final office action on August 9, 2002, in which there was only an enablement rejection. Appellants filed a Notice of Appeal, and on February 11, 2003, filed an Appeal Brief, presenting argument as why the enablement rejection, which was made over the full scope of the claims, was not proper.

In response, the Examiner withdrew the Final Rejection, noting that the claims were not drawn to specific compounds, but to a method of treating sexual dysfunction by administering a human MC-4R agonist (Office Action (mailed June 10, 2003) 2). According to the Examiner, "[w]ithout claiming specific compounds, the metes and bounds of the monopoly grant cannot be ascertained." (*Id.*) The Examiner thus required Appellants to elect a single disclosed species (*id.*).

Appellants elected with traverse the species defined by Example 2 (Paper (dated June 26, 2003)), and the Examiner issued a new office action, rejecting the elected species under double-patenting (Office Action (dated August 26, 2003) 2), and also rejecting the claims under 35 U.S.C. § 112 ¶ 1 for not enabling the full scope of the claims (*id.* at 3) and for lack of adequate written description (*id.* at 6-7). Those rejections were made final (Office Action (dated December 2, 2003)), and presented to the prior panel for review on appeal.

While the prosecution history regarding what was actually examined was unclear, we note the Examiner previously argued: "No structural characteristics of an agonist are provided nor is there any indication that applicant had possession of any such agonist other than the compounds of formula (I) which have already been patented . . . " (Ans. 4-5). In the Request, the Examiner again makes this point (Request 5 ("the examiner explicitly stated that Applicants were in possession of and enabled for not only for the particular species of Example 2 but also for all the species encompassed by formula (I)")). We further note, other than in the context of the double-patenting rejection, the election of species was never again mentioned by either Appellants or the Examiner, and all arguments were consistent with an appeal of the full scope of the claims.

The Examiner's Request was not made until April 16, 2007, a year and five months after the Decision on Appeal was rendered by the prior panel. It is unclear why the Request was filed so late, and normally we would not rehear a case when the request is so tardy. In this case, however, we will do so in the interests of correcting our error and advancing the prosecution of this application. Because the panel misapprehended or overlooked the scope of the claims before it, the Examiner's Request is granted.

FINDINGS OF FACT[2]

Findings of Fact: Background

1. Appealed claims 39 to 73 and 75 are to a method of treating erectile dysfunction (ED) by administering a MC-4R agonist that has a higher affinity for MC-4R than for one or more of MC-1R, MC-2R, MC-3R, and MC-5R. For example, claim 39 requires a higher affinity to MC-4R than to MC-1R, claim 43 requires a higher affinity to MC-4R than to MC-3R, and claim 46 requires a higher affinity to MC-4R than to MC-5R.[3] Thus, the only limitations to the genus of compounds used to treat ED are functional.

2. Specifically, representative claim 39 reads:

> 39. A method of treating erectile dysfunction in a male subject which comprises administering to the subject in need thereof a therapeutically effective amount of a compound which is a human melanocortin-4 receptor (MC-4R) agonist wherein the binding of the compound to the human MC-4R is characterized by an IC_{50} less than 30 nanomolar (nM) and the binding of the compound to the human MC-1R is characterized by an IC_{50} greater than 30 nM.

3. This case is a divisional of U.S. 6,350,760 (the '760 patent), a patent that issued Feb. 26, 2002. The method claims in the '760 patent are like those in the pending case but are limited to a subgenus of compounds,

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[2] Findings of Fact are abbreviated "FF."

[3] Claim 74 does not require that the agonist of MC-4R selectively bind to MC-4R over the other melanocortin receptors. Given Appellants' own teachings (Spec. 3-4), claim 74 appears to be unpatentable under either § 102 or 103. If prosecution is resumed, the Examiner should reconsider the patentability of claim 74 under these statutory provisions.

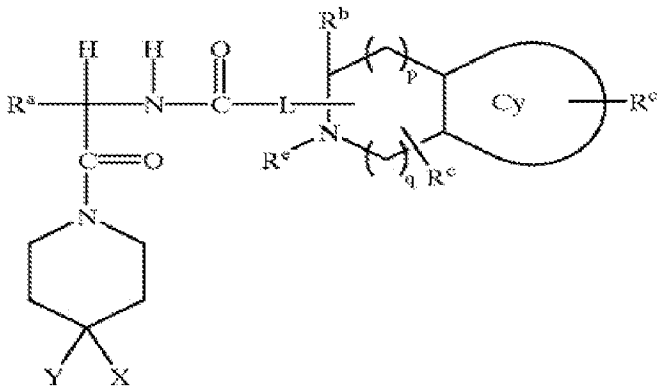
claimed as a generic structure (Formula I). The compounds per se are also claimed.

4. A representative claim of the '760 patent reads:

> 22. A method for the treatment or prevention of erectile dysfunction which comprises administering to a subject in need of such treatment or prevention an effective amount of a compound of claim 1.

5. Claim 1 of the '760 patent reads:

> 1. A compound having the formula I:



> or a pharmaceutically acceptable salt thereof; wherein [the various moieties are expressly defined].

6. Thus, Appellants have received patent protection covering the administration of compounds within formula I (FF 3, 4).

Findings of Fact: The § 112 ¶ 1 Requirements

7. Based on the recitation of "oral administration" in claims 74 and 75, Appellants group these claims separately (App. Br. 3).

8. As there is no allegation that oral administration is a factor in the Examiner's § 112 ¶ 1 grounds of rejection, we review the outstanding

rejections of all the pending claims with reference to representative claim 39. *See* 37 C.F.R. § 41.37(c)(1)(vii)(2006).

9. Representative claim 39 covers a method of treating ED with any compound which acts as an agonist to the human MC-4R with an IC_{50} less than 30 nanomolar (nM) and to human MC-1R with an IC_{50} greater than 30 nM.

10. The generic compounds recited in the pending claims have no structural limitations, and no guidance regarding their structure is given in the Specification, other than identification of formula I.

11. The Examiner states that the claims are enabled and described for formula I (Examiner's Answer (mailed June 22, 2004) (hereafter "Ans.") *passim*; Request 3-5). "Indeed, the Examiner explicitly stated that Applicants were in possession of and enabled for not only the particular species of Example 2 but also for all the species encompassed by formula (I)" (Request 5).

12. Rather, the Examiner disputes enablement and written description for generic compounds *outside of* formula I (*see id.*).

13. "The prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists" but is "silent about what other compounds or families of compounds might be [selective] MC-4R agonists" (Ans. 6).

14. "The only working examples of MC-4R agonists are of formula (I)" (Ans. 6).

15. Appellants have "linked the MC-4R agonism to treating erectile dysfunction in human males" but have not identified any particular structural

characteristics tied to such function that are not also tied to MC-1R agonism, other than those of formula I (Ans. 11).

16. Thus, one skilled in the art, not knowing what compounds to screen, would be required to begin with large chemical collections and libraries of chemical compounds to identify compounds falling within the scope of claim 39, other than those of formula I (Ans. 11).

17. The Examiner finds, "automated methods for drug screening" are available (*id.*).

18. Such screening methods are disclosed in Appellants' Specification (Spec. 35-40).

19. Appellants do not disclose methods for making compounds within the scope of claim 39, other than those of formula I.

20. At the time the claimed invention was made, one skilled in the relevant art would not have recognized Appellants were in possession of the full scope of claim 39 (FF 9-19).

21. The quantity of experimentation required to practice the full scope of claim 39 would have been vast (FF 9-19).

II. The Enablement Issue

"The essential question here is whether the scope of enablement . . . is as broad as the scope of the claim[s]." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991). The answer to this question turns on certain facts. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (describing a number of fact issues known as the "*Wands* factors"). Those most relevant in this case are the breadth of the claims and

the amount of direction given by the inventors in the Specification (*see* FF 9-10, 14-19; Ans. 6). Based on our review of these and other factors identified by the Examiner (Ans. 6), we find the skilled artisan would have been required to unduly experiment in order to practice the full scope of the claims. This is particularly true, given the lack of guidance regarding correlation of structure to the claimed functions for compounds other than those of formula I (FF 9, 10, 13-19, 21; *see also* Request 3). Accordingly, we conclude the claims would not have been enabled for their full scope (FF 9-19, 21).

Appellants argue[4]

> the requirements of § 112, first paragraph, for enablement support for claims to specific chemical compounds or uses thereof is not relevant. Rather the Appellants have discovered a . . . link between MC-4R agonism and induction of penile erections . . . . Briefly, the Appellants have not invented compounds, but a novel method of treating erectile dysfunction in human males.

(App. Br. 6.) The problem we have with this argument is that to practice the full scope of Appellants' broadly-claimed method, the skilled artisan must have been able to make and use the genus of compounds functionally recited in the claims without undue experimentation. Here, without some guidance as to what the compounds are structurally, the skilled artisan would not have been able to identify the genus, other than the subgenus of formula I, without undue experimentation, let alone make such unidentified compounds (*see* FF 19, 21). Thus, while Appellants may not have invented compounds, they

[4] Appellants did not respond to the Examiner's Request. Thus, our opinion and decision are based upon their Brief on Appeal (received Apr. 12, 2004) (hereafter "App. Br.") and their Reply Brief Under 37 C.F.R. 1.193(b) (received Aug. 23, 2004) (hereafter "Reply Br.").

still were required to provide the skilled artisan with sufficient information to identify such compounds without undue experimentation. We find that is not the case here (*see* FF 9-19, 21).

Appellants also argue:

> Appellants' specification clearly sets out a roadmap for the skilled artisan in the pharmacological arts to follow in order to identify compounds which bind selectively to MC-4R and which also function as agonists of MC-4R according to the parameters of Claims 39-75. . . . The ready availability of automated methods for drug screening . . . allows for the routine screening of large chemical collections and libraries of chemical compounds . . . . This type of rapid and automated screening is well within the bounds of one of ordinary skill in the art . . . and does not require "extensive and undue experimentation" . . . .

(App. Br. 6-7.)

We agree with Appellants that some experimentation is permissible, even if extensive (as it would be in this case), "if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224 (CCPA 1977) (Miller, J., concurring), *quoted by* Appellants (App. Br. 7). However, we do not agree with Appellants that their Specification provided such "direction or guidance," except for formula I, for which Appellants have already received patent protection (FF 3-5). Thus, again, we are not persuaded by Appellants' argument.

III. The Written Description Issue

Section 112 ¶ 1 requires an applicant to "provide sufficient written description to show one of skill in the art that the inventor possessed the claimed invention at the time of filing." *University of Rochester v. G.D.*

Searle & Co., 358 F.3d 916, 927 (Fed. Cir. 2004). Possession must be commensurate with the full scope of the claims. *See, e.g., LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (while "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included "to demonstrate that the patentee possessed the full scope of the [claimed] invention").

Many cases have addressed adequacy of written description in the context of biotechnology inventions. *See, e.g., Enzo Biochem. Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Ex parte Kubin*, http://www.uspto.gov/web/offices/dcom/bpai/ prec/fd070819.pdf (BPAI May 31, 2007) (No. 2007-0819) (precedential). The legal analyses applied in those cases apply equally to chemical cases, such as this one. *See, e.g., Rochester*, 358 F.3d at 925-26; *Lilly*, 119 F.3d at 1568 ("written description of an invention involving a chemical genus . . . 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials"). Likewise, the analyses apply to methods as well as compositions of matter. *Rochester*, 358 F.3d at 926. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See Rochester*, 358 F.3d at 927. Thus, the inclusion of screening methods is not enough to meet the written description requirement.

While "the written description requirement can in some cases be satisfied by functional description," that is true only if "there is also a structure-function relationship known to those of ordinary skill in the art." *In re Wallach*, 378 F.3d 1330, 1335 (Fed. Cir. 2004). In this case, Appellants have failed to establish such a relationship was known for the broadly claimed subject matter, other than for that of formula I (FF 9-16). Given the broad scope of the claims and lack of guidance regarding the identity of compounds outside of formula I, we find the claims would not have been adequately described to show possession of their full scope (FF 20).

Appellants argue: "A relationship has been established in the art between the **function** of binding to the family of G-protein-coupled receptors to which MC-4R belongs and the **structure** of potential ligands having affinity for such receptors" (App. Br. 4 (emphasis Appellants')). However, even if true, Appellants do not point to any relationship established in the art, or provided in their Specification, between the claimed function of *selectively* binding MC-4R and the structure of ligands having such *selective* affinity for MC-4R.

Appellants continue this line of argument by naming a number of "structurally diverse variants" known to bind to G-protein-coupled receptors "with the *potential* to function as selective MC-4R agonists" (App. Br. 5 (emphasis added)). Again they fail to point to any structural components of these variants that would provide selective binding/agonism to MC-4R rather than MC-1R, as claimed. In fact, the admitted diversity of such compounds further confirms the difficulty in identifying the structure or

structures responsible for selective binding--the essence of Appellants' claimed invention. Thus, we find Appellants' arguments based on prior art teachings unavailing.

CONCLUSION

We grant the Examiner's Request for Rehearing. Having reheard the case on the written record, supplemented with the Examiner's Request, we affirm the Examiner's § 112 ¶ 1 grounds of rejection of claim 39. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), we also affirm the rejection of claims 40-75, as the additional limitations of these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

ADAMS, *Administrative Patent Judge*, dissenting.

The majority grants the Examiner's Request for Rehearing (Request) and affirms the Examiner's rejections under the written description and the enablement provisions of 35 U.S.C. § 112, first paragraph. I do not dispute the majority's decision to grant the Examiner's Request. However, because the evidence of record fails to support the majority's decision to affirm the rejections under 35 U.S.C. § 112 first paragraph - I dissent.

Findings of Fact (FF):

A. Neither the Examiner nor the majority have established a factual foundation to support the rejections of record (*See, e.g.*, Ans. 3 ("No prior art is relied upon by the examiner in the rejection of the claims under appeal")).

B. There is no dispute on this record that non-selective melanocortin (MC) receptor agonists were known in the art as of Appellants' filing date. In this regard, the majority finds that "[t]he prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists" (Majority Op. 8 (quoting Ans. 6)). Since neither the Examiner nor the majority favor this record by identifying the evidence to support this finding, it can only be presumed that this finding is derived from Appellants' Specification (*see* Spec. 3-4).

C. Melanocortin receptors are G-protein coupled receptors (Spec. 1: 12-13).

D. "A relationship has been established in the art between the **function** of binding to the family of G-protein-coupled receptors to which

MC-4R belongs and the **structure** of potential ligands having affinity for such receptors" (Br. 4).

E. "[P]rivileged [ligand] structures and their affinity for G-protein coupled receptors were well appreciated in the medicinal chemical arts at the time of filing of Appellants' patent application" (Br. 4-5).

F. The compounds of Appellants' formula I are

> 4-substituted piperidines are merely one class of . . . privileged structure scaffolds known in the G-protein-linked receptor art. Other structurally diverse variants outside the scope of formula (I) make up a rich pool of compounds from the G-protein-linked receptor art for evaluation according to the methods described in the instant application.

(Br. 5.)

G. "Appellants' were in possession of and enabled for . . . all the species encompassed by formula (I)" (Majority Op. 8; Request 5).

H. Appellants' Specification provides adequate written descriptive support for compounds within the scope of formula I (*see* Majority Op. 8; Request 3-4; Ans. 4-5).

I. This evidence teaches that a person of ordinary skill in the art, at the time of Appellants' claimed invention, would have recognized that Appellants disclosed a representative example of one class of scaffold, known in the art, upon which a variety of disclosed reactive/functional groups can be added to produce compounds that are selective for MC-4R.

J. Other "privileged" scaffolds were known in the art that could be substituted according to the teachings in Appellants' disclosure to produce compounds that are selective for MC-4R (FF E, F, and H-J).

K. "The methods to be used to identify selective binders of MC-4R are presented on page 35 of the specification, which describes the assays that measure binding affinities to five different melanocortin receptor subtypes" (Br. 7).

L. "[T]he methods needed to determine whether the selective binders of MC-4R also function as selective agonists of MC-4R are provided by a description of the functional assays on page 37 of the specification" (Br. 7).

M. "The ready availability of automated methods for drug screening, such as high-throughput screening (HTS), in the pharmaceutical industry allows for the routine screening of large chemical collections and libraries of chemical compounds to identify compounds with defined biological properties, such as selective activation of human MC-4R" (Br. 7).

N. "This type of rapid and automated screening is well within the bounds of one of ordinary skill in the art of identifying biologically active compounds and does not require 'extensive and undue experimentation'" (Br. 7). The majority finds that Appellants' Specification discloses screening methods for the identification of additional compounds that fall within the scope of Appellants' claimed invention (*see* Majority Op. 9).

O. "[M]ethods to use such MC-4R-selective agonists to treat . . . [male erectile dysfunction] are provided on pages 38-39 of the Specification" (Br. 8).

P. "Example 84 constitutes a working example which clearly illustrates the operability of the present invention" (Br. 8).

Q. "The compound disclosed in Example 84 is representative of compounds that are selective agonists of human MC-4R within the

parameters of the claims which induce penile erections in the rat when administered either by the oral or parenteral route" (Br. 8).

R. The structure of the compounds of formula I as recited in Appellants' Specification corresponds to the functional requirements of Appellants' claimed invention.

S. Appellants compounds of formula I "are merely representative of other structural types known in the art that may also be selective agonists" (Br. 4).

T. The Examiner failed to establish the level of skill and predictability in this art.

U. Claim 39 is drawn to a method of treating erectile dysfunction in a male subject. The method comprises the single step of administering to the subject in need thereof a therapeutically effective amount of a compound which is a human melanocortin-4 receptor (MC-4R) agonist. Claim 39 also requires that the MC-4R agonist binds to:

1. human MC-4R with an IC_{50} less than 30 nanomoloar; and

2. human MC-1R with an IC_{50} greater than 30 nM.

V. Claim 74 is drawn to a method for the oral treatment of erectile dysfunction in a male subject. The method of claim 74 comprises the single step of orally administering to the subject in need there of a therapeutically effective amount of a compound which is an agonist of the human MC-4R. Thus, the compound of claim 74 may be either a selective or non-selective MC-4R agonist.

W. Claim 75 depends from and further limits the compound of claim 74 to a selective agonist of the human MC-4R.

X. The majority correctly finds that despite the Examiner's focus on oral administration at pages 3-4[5] of the Request, there is no allegation that oral administration is a factor in the 35 U.S.C. § 112, first paragraph rejections set forth in the Examiner's Answer.

Enablement:

Enablement is a question of law involving underlying factual inquiries. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999). "[N]othing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971).

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

[5] The Request is not paginated. Accordingly, for the purposes of this opinion, I refer to page numbers as if the Request was numbered consecutively starting with the first page.

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted).

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

In analyzing the *Wands* factors the Examiner draws a series of conclusions. The Examiner asserts that "[t]he claims are drawn to treatment of sexual dysfunction in a male subject with any compound that is a MC-4R agonist" (Ans. 6). While this may be true for claim 74, it is not the case with respect to the remaining claims on appeal (FF U & W). Further, as to the nature of the invention, the Examiner asserts that Appellants'

> invention is drawn to treatment of male erectile dysfunction by using a MC-4R agonist wherein the binding of the compound to MC-4R is characterized by an IC50 of less than 30 nanomolar and the binding of the compound to the human MC-1R is characterized by IC50 greater than 30 nM.

(Ans. 6.) While this may be true for claim 39 it is not true of the remaining claim on appeal (*see e.g.*, FF U-W).

Nevertheless, the majority finds that the breadth of the claims is one of the two most relevant factors on this record (Majority Op. 9-10). I agree with the majority that the breadth of the claims before us are broad (Majority Op. 10). However, determining that Appellants' claims are broad does not end the analysis as one must look to Appellants' Specification to determine

what the disclosure teaches a person of ordinary skill in this art at the time the invention was made.

In this regard, the majority finds that the other "most relevant" factor on this record is "the amount of direction given by the inventors in the Specification" (*id.*). The Examiner asserts that "[t]he inventor has provided direction only for the compounds of formula (I) treating male erectile dysfunction" (Ans. 6). In the majority's words, "one skilled in the art, not knowing what compounds to screen, would be required to begin with large chemical collections and libraries of chemical compounds to identify compounds falling within the scope of claim 39, other than those of formula I" (Majority Op. 9). The Examiner treats the majority's concern under her analysis of the "experimentation needed to make or use the invention based on the content of the disclosure" (Ans. 6 ("The ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims.")).

To come to terms with the claims and disclosure before this panel it is necessary to take a step back and evaluate the claimed invention in the context of the state of the art at the time this invention was made. In this regard, the Examiner and majority find that "[t]he prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists" (FF B). The Examiner asserts, however, that "the art is silent about what other compounds or families of compounds might be MC-4R agonists" (Ans. 6).

The evidence on this record fails to support the Examiner's limited view of the state of this art.

A number of undisputed facts on this record serve to establish the state of the art at the time this invention was made. There is no dispute that the substituted piperidines of formula I are fully enabled by Appellants' disclosure (FF G). It is factually undisputed on this record that MC receptors are G-protein coupled receptors (FF C). It is factually undisputed on this record those of ordinary skill in this art, as of Appellants' filing date, recognized that privileged ligand structures and their affinity for G-protein coupled receptors were known (FF D-J). It is factually undisputed on this record that the 4-substituted piperidines of formula I are one such class of privileged structure scaffold known in the art at the time of Appellants' claimed invention (FF F). It is factually undisputed that different reactive/functional groups can be added to a 4-substituted piperidine scaffold to produce compounds that are selective for MC-4R (FF G). Thus, the prior art teaches scaffolds, such as piperidine and others, that are privileged G-protein coupled receptor ligand structures (FF D-H). Appellants' Specification teaches the substitutents that can be added to these scaffolds to produce compounds that are selective for MC-4R (Spec. 7-10). It is undisputed that Appellants' Specification discloses methods for producing compounds within the scope of the claimed invention that have a piperidine scaffold (FF K-N). In this regard, the Examiner recognizes that Appellants' Specification provides working examples of MC-4R agonists having the structure of formula I (Ans. 6; FF P).

There is no evidence or fact-based reasoned analysis of why, given Appellants' disclosure, it would require undue experimentation for a person of ordinary skill in the art to substitute other known privileged ligand structure scaffolds with the substitutents recited in Appellants' disclosure to arrive at compounds within the scope of Appellants' claimed invention. Simply stated, a Specification in a patent application speaks to those of ordinary skill in the art, 35 U.S.C. § 112, and not to laymen. For the foregoing reasons and contrary to the majority's conjecture[6], there is no evidentiary basis on this record to support a conclusion that a person of ordinary skill in this art would not know what compounds to screen (Majority Op. 9).

Simply stated, the Examiner failed to meet her burden of establishing why the scope of Appellants' claimed invention is not adequately enabled by Appellants' disclosure. On this record, the preponderance of the evidence falls in favor of Appellants. Therefore, I disagree with the majority's factually unsupported assertion that "the skilled artisan would have been required to unduly experiment in order to practice the full scope of the claims" (Majority Op. 10). Further, for the foregoing reasons, I disagree with the majority's assertion that "without some guidance as to what the compounds are structurally, the skilled artisan would not have been able to identify the genus, other than the subgenus of Formula I, without undue experimentation, let alone make such unidentified compounds" (*id.*).

There is no evidence on this record to suggest that it would require undue experimentation to substitute these same moieties onto another art

[6] What the majority calls findings of fact are nothing more than the Examiner's unsupported conjecture.

recognized privileged G-protein coupled receptor ligand scaffold, with the expectation of obtaining an MC-4R analog within the scope of Appellants' claimed invention.

As to the predictability in the art, rather than provide an evidentiary basis to support her position, the Examiner attempts to improperly shift her evidentiary burden to Appellants (Ans. 6 ("It has not been shown that there is any level of predictability in the art.")). While the majority may find this sufficient, I find that the burden of proof does not shift to Appellants until the Examiner first meets her burden of establishing a prima face case of non-enablement. *Marzocchi*, 439 F.2d at 223-224. This has not been done on this record.

Because the Examiner failed to meet her burden the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph should be reversed.

Written Description:

Whether or not a Specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph is a question of fact, which must be resolved on a case-by case basis and judged from the perspective of one of ordinary skill in the art as of the relevant filing date. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991). A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it

from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). This requirement applies not only to compositions of matter but to methods as well. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004). However,

> the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005). "The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance." *In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978).

The Examiner has not met her burden on this record and the facts on this record do not support the majority's conclusion.

The facts on this record are distinct from those in *Rochester*. In *Rochester*, our appellate reviewing court found that

> because the '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods-an essential element of every claim of that patent-and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention.

Rochester, 358 F.3d at 929. The *Rochester* court found that "the '850 patent discloses nothing more than a hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it." *Rochester*,

358 F.3d 926-27. In contrast, on this record both the majority and the Examiner find that Appellants' Specification provides adequate written descriptive support for compounds within the scope of formula I (FF G). Thus, contrary to the facts in *Rochester*, on this record it is *undisputed* that Appellants' Specification discloses compounds that can be used in the claimed methods. *Cf. Rochester*, 358 F.3d at 927.

The structure of the compounds recited in Appellants' Specification correspond to the functional requirements of Appellants' claimed invention (FF P). Therefore, contrary to the majority's assertion, Appellants have provided the requisite structure-function relationship required by *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (*Cf.* Majority Op. 13). In addition, the majority recognizes that Appellants' Specification discloses screening methods for the identification of additional compounds that fall within Appellants' claimed genus (FF K-N). All of this is undisputed.

Nevertheless, despite Appellants' disclosure of specific representative compounds, a structural and functional relationship of compounds within the scope of their claimed invention, and screening methods; the majority and the Examiner assert that Appellants have not provided an adequate written description of the full scope of the claimed invention (Majority Op. 13; Request 3-4; Ans. 4-5). The majority's conclusion is based on two lines of reasoning.

First, the majority finds that Appellants failed to establish that a structure-function relationship "was known for the broadly claimed subject

matter, other than for that of Formula I" (Majority Op. 13). This assertion is unsupported by the evidence on this record.

According to Appellants the formula I compounds "are merely representative of other structural types known in the art that may also be selective agonists" (Br. 4). In support of this assertion, Appellants direct attention to two review articles and explain that "[a] relationship has been established in the art between the **function** of binding to the family of G-protein-coupled receptors to which MC-4R belongs and the **structure** of potential ligands having affinity for such receptors" (*id.*; FF D). According to Appellants these so-called "privileged [ligand] structures and their affinity for G-protein coupled receptors were well appreciated in the medicinal chemical arts at the time of filing of Appellants' patent application" (FF E).

The majority dismisses Appellants' fact-based response by simply asserting that "Appellants do not point to any relationship established in the art, or provided in their Specification, between the claimed function of *selectively* binding MC-4R and the structure of ligands having such *selective* affinity for MC-4R" (Majority Op. 13). Apparently, the majority missed Appellants' discussion at pages 4-5 of the Brief as discussed in the preceding paragraph.

To recap, Appellants' Specification discloses compounds within the scope of the claimed invention. These compounds establish a structure-function relationship for compounds having the ability to selectively bind MC-4R (FF R). Appellants assert that these compounds are representative of the compounds known in the art and directs attention to review articles to support this position. Neither the majority nor the Examiner address the

evidence presented by Appellants. For her part, the Examiner relies on conjecture rather than evidence to support her position (FF A). Serving only to compound the factual deficiency on this record, the majority refers to the Examiner's conjecture as fact (Majority Op. 7-9). Accordingly, there can be no doubt that the preponderance of the evidence on this record falls in favor of Appellants.

Second, the majority focuses on Appellants statement that

> 4-substituted piperidines are merely one class of . . . privileged structure scaffolds known in the G-protein-linked receptor art. Other structurally diverse variants outside the scope of formula (I) make up a rich pool of compounds from the G-protein-linked receptor art for evaluation according to the methods described in the instant application.

(Br. 5; FF F.) According to the majority, Appellants "fail to point to any structural components of these variants that would provide selective binding/agonism to MC-4R rather than MC-1R, as claimed" (Majority Op. 13). The majority clearly misses the point.

The preponderance of the evidence on this record is provided by Appellants. It is factually undisputed that this evidence teaches that:

1. a person of ordinary skill in the art, at the time of Appellants' claimed invention, would have recognized that Appellants disclosed a representative example of one class of scaffold, known in the art, upon which a variety of different reactive/functional groups can be added to produce compounds that are selective for MC-4R; and

2. Other "privileged" scaffolds were known in the art that could be substituted according to the teachings in Appellants' disclosure to produce compounds that are selective for MC-4R (FF C-N).

To rebut this factual evidence, both the majority and the Examiner rely upon mere conjecture. Accordingly, the preponderance of evidence on this record falls in favor of Appellants.

As to compounds within the scope of claim 74 that are non-selective MC-4R agonists, the majority finds that "[t]he prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists" (FF B). It is unnecessary for the Specification to provide a description of compounds which are already known in the prior art. *Capon*, 418 F.3d at 1357-58.

I recognize that Appellants group claim 75 together with claim 74. Claim 75 is drawn to a method of using a selective agonist of the human MC-4R. As such, the rejection of claim 75 should be reversed for the reasons as set forth above.

For the foregoing reasons, the Examiner failed to meet her burden of establishing a prima facie case under the written description provision of 35 U.S.C. § 112, first paragraph. Accordingly, the written description rejection should be reversed.

Examiner's Recourse:

I recognize the Examiner's assertion that a reversal "places the [E]xaminer and the Office in the untenable position of having no other recourse than to allow claims of broader scope than adequately described" (Request 5). I disagree. As set forth in the Manual of Patent Examining Procedure (MPEP) § 1214.04:

> A complete reversal of the examiner's rejection brings the case up for immediate action by the examiner.
>
> . . .
>
> If the examiner has specific knowledge of the existence of a particular reference or references which indicate non-patentability of any of the appealed claims as to which the examiner was reversed, he or she should submit the matter to the Technology Center (TC) Director for authorization to reopen prosecution under 37 CFR 1.198 for the purpose of entering the new rejection. See MPEP § 1002.02(c) and MPEP § 1214.07. The TC Director's approval is placed on the action reopening prosecution.

Therefore, contrary to the Examiner's intimation, if the Examiner has an evidentiary basis for reopening prosecution, the Examiner is free to do so upon approval of her Technology Center Director. As the record stands before this panel neither the majority nor the Examiner have an evidentiary basis to sustain the rejections of record.

Conclusion:

In conclusion I find that the Examiner and the majority have failed to provide an evidentiary basis to support their holding that Appellants' Specification fails to satisfy the written description and enablement

provisions of 35 U.S.C. § 112, first paragraph. Further, assuming *arguendo* that the Examiner did establish a prima facie case of nonenablement and lack of written descriptive support, the Examiner and the majority failed to consider Appellants' rebuttal evidence. *Cf. In re Sullivan*, 498 F.3d 1345. 1353 ("By failing to consider the submitted evidence, the Board thus committed error"); *see also In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986). Here both the Examiner and the majority failed to consider the evidence submitted by Appellants (Br. 4). Accordingly, the majority's opinion is erroneous as a matter of law and fact.

Ssc:

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